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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/835,099 | 04/12/2001 | R. Shoshana Bamdad | M01015/70034 TJO | 2967 |

23628 7590 07/30/2002

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| EXAMINER |
|---|
| KWON, BRIAN YONG S |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Heme-peptide

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/835,099 | BAMDAD ET AL. | |
| | Examiner | Art Unit | |
| | Brian S Kwon | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 April 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-123* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23 and 105-123, drawn to a method of treating a human susceptible to conditions characterized by aggregate-forming species associated with a disease, by administering a composition having a high net polarization, classified in class 514, subclass 635, 332, 335, 315, 359, etc....

II. Claims 24-34, drawn to a method of monitoring or determining an efficacy of a composition having a high net polarization in inhibiting aggregate formation in a sample from the patient, classified in class 435, subclass 7.9, 7.92; class 436, subclass 518.

III. Claims 35-104, drawn to a kit comprising said composition having a high net polarization, classified in class 422.

Inventions I and II are distinct, each from the other because they have different functions given above and have acquired a separate status in the art by their different classification.

Invention III is distinct from Invention II or Invention III because the claimed kit composition can be used in a materially different process of using that product such as for the treatment of hypertension, gastric ulcer, Guillain-Barr Syndrome, depression, glaucoma, mood disorder, etc...

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

If Applicant elects the Group I invention, it is subjected to further restriction as followings.

I(a) Claims 1-23 and 105-123, drawn to a method of treating a human susceptible to conditions characterized by aggregate-forming species associated with a disease, by administering a composition having a high net polarization represented by an aromatic ring structure, classified in class 514, subclass 635, 531, 527. 524.

I(b) Claims 1-23 and 105-123, drawn to a method of treating a human susceptible to conditions characterized by aggregate-forming species associated with a disease, by administering a composition having a high net polarization represented by a pyridine structure, classified in class 514, subclass 332, 335.

I(c) Claims 1-23 and 105-123, drawn to a method of treating a human susceptible to conditions characterized by aggregate-forming species associated with a disease, by administering a composition having a high net polarization represented by a piperidine structure, classified in class 514, subclass 315.

I(d) Claims 1-23 and 105-123, drawn to a method of treating a human susceptible to conditions characterized by aggregate-forming species associated with a disease, by administering a composition having a high net polarization represented by a five membered ring including at least one heteroatom, classified in class 514, subclass 359, 438, 461.

I(e) Claims 1-23 and 105-123, drawn to a method of treating a human susceptible to conditions characterized by aggregate-forming species associated with a disease, by administering a composition having a high net polarization represented by at least two rings bridged by at least one atom, classified in class 514, subclass 281,

I(f) Claims 1-23 and 105-123, drawn to a method of treating a human susceptible to conditions characterized by aggregate-forming species associated with a disease, by administering a composition having a high net polarization represented by at least two rings bonded directly to each other, classified in class 514, subclass 225, 227, 245, 262, etc...

I(g) Claims 1-23 and 105-123, drawn to a method of treating a human susceptible to conditions characterized by aggregate-forming species associated with a disease, by administering a composition having a high net polarization represented by a ring containing at least one carbonyl, classified in class 514, subclass 44-46, 49.

I(h) Claims 1-23 and 105-123, drawn to a method of treating a human susceptible to conditions characterized by aggregate-forming species associated with a disease, by administering a composition having a high net polarization represented by an alkyl chain, classified in class 514, subclass 135.

If Applicant elects the Group II invention, it is subjected to further restriction as followings.

II(a) Claims 24-34, drawn to a method of drawn to a method of monitoring or determining an efficacy of a composition having a high net polarization represented by an aromatic ring structure in inhibiting aggregate formation in a sample from the patient.

II(b) Claims 24-34, drawn to drawn to a method of drawn to a method of monitoring or determining an efficacy of a composition having a high net polarization represented by a pyridine structure in inhibiting aggregate formation in a sample from the patient.

II(c) Claims 24-34, drawn to a method of monitoring or determining an efficacy of a composition having a high net polarization represented by a piperidine structure in inhibiting aggregate formation in a sample from the patient,

II(d) Claims 24-34, drawn to drawn to a method of drawn to a method of monitoring or determining an efficacy of a composition having a high net polarization represented by a five membered ring including at least one heteroatom in inhibiting aggregate formation in a sample from the patient.

II(e) Claims 24-34, drawn to drawn to drawn to a method of drawn to a method of monitoring or determining an efficacy of a composition having a high net polarization represented by by at least two rings bridged by at least one atom in inhibiting aggregate formation in a sample from the patient.

II(f) Claims 24-34, drawn to drawn to drawn to a method of drawn to a method of monitoring or determining an efficacy of a composition having a high net polarization represented by at least two rings bonded directly to each other in inhibiting aggregate formation in a sample from the patient.

II(g) Claims 24-34, drawn to drawn to a method of drawn to a method of monitoring or determining an efficacy of a composition having a high net polarization represented by a ring containing at least one carbonyl in inhibiting aggregate formation in a sample from the patient.

II(h) Claims 24-34, drawn to drawn to a method of drawn to a method of monitoring or determining an efficacy of a composition having a high net polarization represented by an alkyl chain in inhibiting aggregate formation in a sample from the patient.

If Applicant elects the Group III invention, it is subjected to further restriction as followings.

III(a) Claims 35-60 and 101, drawn to a kit comprising a composition having a high net polarization represented by an aromatic ring structure.

I(b) Claims 35-40, 61-63 and 101, drawn to a kit comprising a composition having a high net polarization represented by a pyridine structure.

I(c) Claims 35-40, 64-73 and 101, drawn to a kit comprising a composition having a high net polarization represented by a piperidine structure.

I(d) Claims 35-40, 74-91 and 101, drawn to a kit comprising a composition having a high net polarization represented by a five membered ring including at least one heteroatom. .

I(e) Claims 35-40, 92-95 and 101, drawn to a kit comprising a composition having a high net polarization represented by at least two rings bridged by at least one atom.

I(f) Claims 35-40 and 101, drawn to a kit comprising a composition having a high net polarization represented by at least two rings bonded directly to each other.

I(g) Claims 35-40, 96-98 and 101, drawn to a kit comprising a composition having a high net polarization represented by a ring containing at least one carbonyl.

I(h) Claims 35-40 and 99-101, drawn to a method of treating a human susceptible to conditions characterized by aggregate-forming species associated with a disease, by administering a composition having a high net polarization represented by an alkyl chain.

3. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (e.g., Specific Examples in the specification) from under the instant claims of the elected Group. Moreover, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon.

With the election of a specific exemplified compound, a generic concept will be identified by the examiner as the inventive group for examination.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREH FAY**
**PRIMARY EXAMINER**
**GROUP 1600**